Switching to Janssen's Symtuza Is Safe and Effective Up to 96 Weeks

Researchers compared switching to Symtuza with staying on an effective regimen of a boosted protease inhibitor plus Truvada.

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For those people with HIV on an effective antiretroviral regimen of a boosted protease inhibitor plus Truvada (tenofovir disoproxil fumarate/emtricitabine), switching to Janssen's newly approved Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) is safe and effective according to 96-week data from a recent trial.

Symtuza contains an updated version of Gilead Sciences' drug tenofovir, called tenofovir alafenamide (TAF), that studies have indicated is safer for the bones and kidneys than the older version of the drug, tenofovir disoproxil fumarate (TDF), contained in Truvada. Recent research has suggested that TAF may have a true, clinically significant safety advantage over TDF only when both drugs are given with a boosting agent, either Norvir (ritonavir) or Tybost (cobicistat), as was the case in the trial of Symtuza.

Presenting their findings at the IDWeek 2018 conference in San Francisco, researchers conducted a randomized, open-label, international, multicenter, parallel-group noninferiority Phase III trial called EMERALD that enrolled 1,141 people with HIV who were on a stable regimen of a boosted protease inhibitor plus Truvada and who were ultimately included in the previously reported 48-week analysis. The boosted protease inhibitor could be Kaletra (lopinavir/ritonavir), or it could be Reyataz (atazanavir) or Prezista (darunavir) boosted by either Norvir or Tybost.

The participants needed to have had a viral load below 50 for at least two months upon entry into the study and no more than one viral load of between 50 and 199 for the 12 months prior to their screening visit.

The study members were randomized two to one to switch to Symtuza or stay on their current regimen.

Forty-eight week findings were presented at the 2017 IDWeek conference in San Diego. Twenty-four week findings were presented at the 9th International AIDS Society Conference on HIV Science in Paris (IAS 2017).

Of the 1,141 people included in the 48-week analysis, 1,080 continued in the study through its 96-week extension phase, during which those who received Symtuza stayed on that regimen and those who had been randomized at the study's outset to stay on their current regimen switched to Symtuza at week 52. Consequently, the group that switched to Symtuza on a delayed basis received 44 weeks of treatment on that regimen by the end of the 96-week study period.

Through 96 weeks of treatment, 3.1 percent (24/763) of those who started Symtuza immediately experienced virologic rebound at some point. Ninety-one percent (692 of 763) of the immediate-switch group had a viral load below 50 and 1 percent (9 of 763) had virologic failure at the 96-week mark.

No one developed viral mutations associated with resistance to Prezista (darunavir), their primary protease inhibitor, tenofovir or emtricitabine during the study.

Symtuza was well tolerated, with 9 percent (66 of 763) experiencing serious adverse health events and 2 percent (17 of 763) discontinuing treatment because of adverse health events through 96 weeks of treatment.

The most common adverse events, experienced by at least 10 percent of participants receiving Symtuza in the immediate-switch group, included upper respiratory tract infection (16 percent) viral upper respiratory tract infection (13 percent), diarrhea (11 percent), headache (10 percent) and back pain (10 percent).

Improvements in markers of kidney and bone health reported in earlier findings from the study persisted through the 96-week mark.

Among those who switched to Symtuza at the 52-week point and who were treated with the regimen for 44 weeks, 2.3 percent (8 of 352) experienced virologic rebound at any time. Forty-four weeks after switching to Symtuza, 94 percent (330 of 352) had a viral load above 50 and 2 percent (6 of 352) had virologic failure.

The members of the delayed-switch group experienced improvements in markers of kidney and bone health and a small change in their ratio of total cholesterol to HDL cholesterol, consistent with known effects of switching from the TDF to the TAF form of tenofovir.

To read a press release about the study, click here.

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